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**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

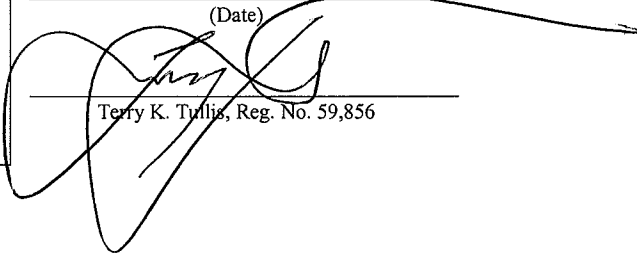
Applicant : John S. Honeycutt, et al.  
App. No : 09/737,165  
Filed : December 14, 2000  
For : ROTATIONAL ATHERECTOMY  
DEVICE  
Examiner : Kevin T. Truong  
Art Unit : 3734

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Terry K. Tullis, Reg. No. 59,856

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Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Dear Sir:

Applicant respectfully requests review of the final rejection set forth in the Final Office Action ("Office Action") dated June 29, 2007 in the above-identified application. Applicants' claims have been twice rejected, and as such Applicants may appeal the examiner's decision to the Board of Patent Appeals and Interferences. No amendments are being filed with this request. Enclosed with this Request is a Notice of Appeal.

**REASONS FOR REQUEST**

The Examiner maintains the rejection of Claims 1-10, 21, 29-33, 65-71, and 74-75 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,779,721 to Nash. The Examiner's rejection contains both clear errors of fact and omissions of essential elements needed for a prima facie rejection. The Examiner's errors relate to erroneously characterizing the Nash reference, thereby resulting in a failure to identify the specific teachings needed to set forth an anticipation rejection. The Examiner's errors are indisputable and not subject to interpretation, and, therefore, must be reversed.

**Claims 1 and 60**

With respect to Claims 1 and 60, the Examiner asserts that Nash discloses an indicator “for indicating resistance to rotation of the rotatable cutter having a sensor in which [sic] equivalent to the claimed indicator.” Office Action at p. 3. The Office Action states that “Nash discloses in figures 1-3, ... a sensor (located at 28, 74, 76) in electrical communication with a [sic] an indicator for indicating resistance to rotation of either to [sic] rotatable element (42) or rotatable cutter (32).” Office Action p. 2. In the rejection the Examiner has provided no specific example of where in Nash the device indicates resistance to rotation. Rather, as evidence of disclosure of this claim limitation, the Examiner has provided a reference to about two columns of the Nash specification (col. 8 line 20 to col. 9 line 37). In the Examiner’s cited passage of Nash, the atherectomy device is powered by an air turbine motor (70) that drives the drive sub-system (28). Air is provided from a source (not shown) via an associated regulator (74) and a conventional control valve (76). A pressure gauge (78) is provided in the air supply circuit upstream of the valve (76). There is no description in Nash of structure that indicates any resistance to rotation. The only measuring structure in this circuit, the pressure gauge (78), is not necessarily balanced with valve flow, turbine, and connecting conduit resistance such that the combination might potentially indicate resistance to rotation, if indeed it were even possible to do so.

Applicant’s arguments as summarized above were presented in the Response filed April 17, 2007, pages 8-9 and 11-12, but were unaddressed in the Final Office Action. Rather, the Final Office Action merely repeated the same rejection made in the Office Action of January 18, 2007, with no additional explanation. In view of the Examiner’s factual mischaracterization of Nash, the Examiner has omitted essential elements needed for an anticipation rejection of Claims 1 and 60.

**Claim 21**

With respect to Claim 21, the Examiner asserts that Nash discloses an aspiration lumen that is sized to be “at least 35% of the cross-sectional area of the tubular body.” The Office Action fails to identify the disclosure, specific teaching or suggestion in Nash in support of this rejection, and Applicant was unable to identify any such support. The Examiner asserts that the space between the outer surface of the catheter (22) and the inner surface of the guide catheter (24) defines an aspiration lumen (Q2). However, as discussed in detail in the Office Action

Response of April 17, 2007 at pages 9-10, it is impossible to determine the cross-sectional area based on a lack of Nash dimensional disclosure of the interior surface of the guide catheter (24).

Furthermore, the Examiner improperly rejects Claim 21 by relying solely on figures 2 and 3 for “clearly shown ... cross-sectional area” to characterize a space (“Q2”) between the atherectomy catheter (22) and the guide catheter (24) as comprising at least 35% of the cross-sectional area of the tubular body. Nash does not state that the drawings are to scale, and “when the reference does not disclose that the drawings are to scale and is silent as to dimensions, arguments based on measurement of the drawing features are of little value.” See M.P.E.P. § 2125 (citing *Hockerson-Halberstadt, Inc. v. Avia Group Int'l*, 222 F.3d 951, 956, 55 USPQ2d 1487, 1491 (Fed. Cir. 2000)). Thus, support for the rejection cannot be based solely on the drawings, and Applicant respectfully submits that there is no basis for the rejection.

#### **Claim 29**

Claim 29 recites, among other things, “a rotatable cutter disposed within the tubular body at the distal end of the body.” The Examiner asserts that “Nash’s working head (32) is clearly disposed within the tubular body (24), wherein shroud (56) is considered part of the tubular body (24). However, the shroud 56 in Nash is clearly shown to be separate from the tubular body 24 (see Fig. 2). This is further explained in Applicant’s response of April 17, 2007, page 10. Thus, the Nash working head (32) is not “disposed within the tubular body,” and the Examiner has omitted an essential element needed for an anticipation rejection.

Claim 29 also recites, among other things, “an axially extending annular aspiration channel defined by and located between the rotatable element and the tubular body.” As defined by the Examiner, Nash has an axially extending annular aspiration channel (Q2) extending between the atherectomy catheter 22 and the guide catheter 24. This channel does not extend between the Nash rotatable element (42) and the tubular body (22 or 24), as discussed in Applicant’s Response of April 17, 2007, page 11. The Examiner has failed to identify how this claim limitation is satisfied by Nash, and therefore, has failed to establish a prima facie case for anticipation.

#### **Claim 65**

With respect to Claim 65, pages 2 and 3 of the Examiner’s Final Office Action rejection fails to identify any disclosure in Nash that describes a “connecting hub coupling the tubular body to the control such that the tubular body may rotate relative to the control during

operation.” The Examiner points to Figure 1 of Nash, but provides no explanation whatsoever for how the tubular body in Nash may rotate relative to the control during operation.

As explained in Applicant’s Response of April 17, 2007, page 5, Nash fails to teach a hub that permits rotation relative to the control and that is disposed on the proximal end of the tubular body. The Examiner identifies a “control or hub (66)” as equivalent structures. Office Action p. 2. Nash describes “a conventional Y connector 66 ... [that] has one input leg including a Touhy-Borst adjustable hemostasis valve 66A through which the atherectomy catheter 22 passes. The other input leg, i.e., the angled leg 68, is connected to the aspiration portion of the debris removal sub-system 30.” Nash col. 8, ll. 12-18. Nash does not disclose, teach or suggest that the Y connector (66) is rotatable with respect to itself, and the Examiner’s Office Action fails to identify any structure in Nash whatsoever corresponding to the recited claim limitations.

#### **Claim 68**

With respect to Claim 68, Nash does not disclose, teach, or suggest a cutter that is capable of axial displacement with respect to a control during operation. As with Claim 65, the Examiner fails to identify any disclosure in Nash that describes this claim limitation. Instead, the Examiner simply argues that Claim 68 “should be given its broadest reasonable interpretation, for this reason, the cutter of Nash is clearly capable of being [sic] axial displacement relative to the control during operation.” Office Action, p. 3. Even giving Claim 68 its broadest reasonable interpretation, the Examiner must still point out disclosure in Nash of a cutter that is capable of axial displacement with respect to a control during operation to make out an anticipation rejection. That the Examiner has failed to do so omits an essential element necessary for the prima facie rejection.

Furthermore, as explained at pages 12 and 13 of Applicant’s response of April 17, 2007, Nash states, “[t]he working head is located within a cylindrical shroud 56 (FIGS. 3 and 4) fixedly mounted on the front of the bushing 38.” Nash col. 7, ll. 14-16. The Nash cutter has a specific position within the shroud 56 to create a differential flow of infusate liquid to establish an unbalanced flow adjacent the working head to enable the catheter to be steered hydrodynamically and to aspirate debris from the working field of the instrument. Nash Abstract. Specifically, Nash states, “[t]he rotation of the working head about its longitudinal axis produces a powerful toroidal shaped vortex flow Q3 in the fluid contiguous with the working head. This flow Q3 circulates by entering into the shroud through the central or front

opening 62 and exits out through the side window 64 as shown in FIG. 3.” Nash col. 7, ll. 35-40. If the Nash cutter is axially advanced or withdrawn, the device may not perform the intended function. Thus, Applicant respectfully submits that Nash fails to disclose, teach, or suggest a device in which the cutter is capable of axial displacement relative to a control and that the reference does not anticipate Claim 68 under 35 U.S.C. § 102(e).

**Dependent Claims**

Claims 2-10, 30-33, 61-64, 66-67, 69-71, 74 and 75 which depend from Claims 1, 21, 29, 60, 65 and 68, are believed to be patentable for the same reasons articulated above with respect to Claims 1, 21, 29, 60, 65 and 68, and because of the additional unique features recited therein. Accordingly, it is respectfully submitted that Nash does not teach or suggest all the limitations of these claims or the independent claims from which these claims depend, and withdrawal of the rejection under 35 U.S.C. § 102(e) is respectfully requested.

**Conclusion**

In view of the foregoing, Applicants respectfully submit that the anticipation rejection of the pending claims is improper. The rejections rely on the Examiner’s clear errors and omissions, and must be reversed. Accordingly, the claims are in condition for allowance. Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 9-27-07

By: 

Terry K. Tullis  
Registration No. 59,856  
Attorney of Record  
Customer No. 20,995  
(949) 760-0404